

II. RESPONSE TO OFFICE ACTION

A. Status of the Claims

Claims 39, 40, 46, 47, 63-66, 68-83, and 88 were rejected by the final Office Action dated June 18, 2008. Applicants have cancelled claims 65 and 69-78 (11 claims) and added claims 93-101 (9 claims). Claims 39 and 68 have been amended. Support for the added and amended claims can be found in the specification at least at pages 166-169 (Examples showing cells with wild-type and mutant Fortilin, some of which concern etoposide-induced cell death) and in the originally filed claims 39-47.

B. Interview Summary

Applicants and their representative sincerely appreciate the time and consideration given by Examiner Angell and Supervisor Schultz in a telephone interview with Applicants' representative on August 11, 2008. During that interview, the rejections under 35 U.S.C. §112, first paragraph, for written description and enablement were discussed. Supervisor Schultz offered a different basis for the enablement rejection than was set forth in the pending Action. While resolution was not reached during the interview, further clarity of the grounds for the rejection were obtained and Applicants are submitting this amendment and response to address these.

C. Reconsideration of Finality of Office Action

Applicants note that the previous Office Action mailed on September 9, 2007 raised new rejections under 35 U.S.C. § 112, first paragraph, after the Applicants had previously adopted the Examiner's suggestions for amending the claims to overcome all of the previous rejections. Applicants further note that these rejections had not been made in response to the amendments and that this application has been pending since 2001. Applicants sincerely hope that the merits of this case will be considered fairly and efficiently to avoid further delay in securing valid

patent protection for the Applicants' invention. In particular, Applicants respectfully request that the Examiner re-consider the finality of the Office Action because Applicants have earnestly attempted to reach accord with the Examiner, as is demonstrated by the current response in view of statements articulated during the interview.

D. Claims 39, 40, 63-66, 68-70, 73-83, and 88 Are Adequately Described

The Action rejects claims 39, 40, 63-66, 68-70, 73-83, and 88 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. It contends that the claims encompass methods that require assaying Fortilin polypeptide activity *in vitro* or in a cell and that the claims encompass a genus of Fortilin activities of indeterminate size. Applicants respectfully traverse this rejection.

Applicants note that the Written Description Guidelines indicate there is a “**strong presumption** that an adequate description of the claimed invention is present in the specification as filed.” Guidelines for the Examination of Patent Applications Under 35 U.S.C. §112, ¶ 1, “Written Description” Requirement at II.A (emphasis added). Moreover, patent law states that the Examiner has the initial burden of presenting evidence or reasons for an inadequate written description requirement. *See In re Wertheim*, 541 F.2d 257 (C.C.P.A. 1976). Additionally, “an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.” *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336 (Fed. Cir. 2001).

The Action acknowledges that Fortilin activity is provided in that the specification describes that Fortilin induces apoptosis, that it binds to p53, and that it binds MCL1. There is no evidence or any indication of *other* binding activities of Fortilin to support the contention that there are activities of Fortilin not described. It cannot be sufficient to make a rejection based on a completely hypothetical situation—that there *may be* other binding activities of Fortilin.

For the foregoing reasons, the written description rejection is without merit and Applicants respectfully request that it be withdrawn.

E. Claims 39, 40, 63-66, 68-70, 73-83, and 88 Are Enabled

The Action rejects claims 39, 40, 63-66, 68-70, 73-83, and 88 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The grounds for this rejection are similar to the grounds asserted for the written description rejection. Essentially, the Action that the claims encompass methods that require assaying Fortilin polypeptide activity *in vitro* or in a cell and that the claims encompass a genus of Fortilin activities of indeterminate size. The Action further argues that full scope of the claims would require undue experimentation to practice because the specification teaches only that Fortilin binds p53 and it binds MCL1 polypeptide. Applicants respectfully traverse this rejection.

Applicants have described a method involving measuring Fortilin activity (*i.e.*, apoptosis) and they have described how this can be achieved in their specification, for instance, in Examples 3 and 8. In addition, the skilled person could use p53 binding or MCL1 binding to evaluate Fortilin activity.

Furthermore, methods for measuring apoptosis and binding were well known to those of skill in the art at the time the application was filed. “The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available in the public.” MPEP 2164.05(a) (citing *inter alia*, *In re Buchner*, 929 F.2d 660, 661, 18 U.S.P.Q. 2d 1331, 1332 (Fed. Cir. 1991)). Consequently, it cannot be alleged that it would require undue experimentation to practice the invention. The Action provides no evidence either from the specification or art that even suggests Fortilin may have other activities. That the skilled artisan would have to practice undue experimentation to determine whether Fortilin has *other* activities is without any basis in the law.


Moreover, the claims set forth a basis for determining that modulation of specifically Fortilin is occurring. Accordingly, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn so they may pass to issuance.

Should the Examiner have any questions or comments or identify any issues that can be readily addressed in a conversation with Applicants' representative, I request that he please contact me at 512-536-3081.

Respectfully submitted,


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